Remarks

Claims 1-5 are pending in this application. Claims 4 and 5 have been withdrawn from consideration. Claim 3 has been canceled without prejudice. Claims 1-2 have been amended in various particulars as indicated hereinabove. New Claim 6 hase been added to alternatively define the invention.

Claims 1-3 were rejected under 35 U.S.C. 112, second paragraph.

Applicants believe that the claims as amended are in compliance with 35 U.S.C. 112, second paragraph. In particular, it has been clarified that the claimed medicament comprises one or more homeopathic dilutions. Illustrative Example 1 in the specification discloses two homeopathic dilutions used in a treatment regimen. Illustrative Example 2 in the specification describes three homeopathic dilutions administered to a patient. Illustrative Examples 3, 4, 6 and 8 describe a medicament comprising one homeopathic dilution administered to a patient. Illustrative examples 5 and 7 describe a medicament comprising three homeopathic dilutions administered to a patient.

With regard to the terms "homeopathic dilutions of a potentiated form…antibodies" now present in the Claims, Applicants provide the following explanation. The Patent Office is asked to refer to the report on "Q&A about Homeopathy", issued by the National Center for Complementary and Alternative Medicine of the National Institute of Health (NIH) (copy enclosed). On page 2 of the enclosed copy, the NIH report explains (emphasis added):

"In the late 1700s, Samuel Hahnemann, a physician, chemist, and linguist in Germany, proposed a new approach to treating illness."

"Hahnemann added two additional elements to homeopathy:

- A concept that became **"potentization,"** which holds that systematically diluting a substance, with vigorous shaking at each step of dilution, makes the remedy more, not less, effective by extracting the vital essence of the substance. If dilution continues to a point where the substance's molecules are gone, homeopathy holds that the "memory" of them--that is, the effects they exerted on the surrounding water molecules--may still be therapeutic.

- A concept that treatment should be selected based upon a total picture of an individual and his symptoms, not solely upon symptoms of a disease. Homeopaths evaluate not only a person's physical symptoms but her emotions, mental states, lifestyle, nutrition, and other aspects. In

> homeopathy, different people with the same symptoms may receive different homeopathic remedies.
>
> Hans Burch Gram, a Boston-born doctor, studied homeopathy in Europe and introduced it into the United States in 1825. European immigrants trained in homeopathy also made the treatment increasingly available in America. In 1835, the first homeopathic medical college was established in Allentown, Pennsylvania. By the turn of the 20th century, 8 percent of all American medical practitioners were homeopaths, and there were 20 homeopathic medical colleges and more than 100 homeopathic hospitals in the United States. "

As follows from the above, the concept of potentization as extreme dilution and that a remedy is prepared by extremely diluting the substance in a series of steps has been known and well defined in the US since at least the first half of the 19th century. Homeopathy asserts that this process can maintain a substance's healing properties regardless of how many times it has been diluted. Many homeopathic remedies are so highly diluted that not one molecule of the original natural substance remains in the dilution. Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. While no definite scientific theory exists to explain how potentiated remedies work, it has been known that they work, along with the well known term "potentiated", defining such remedies. Please refer to the Rule 132 Declaration of inventor Oleg Epshtein providing additional experimental data on the efficacy of the claimed medicament and the research behind those data. The introduced Claim amendments are also supported by paragraphs [0007]-[0008, [0010]-[0012] and [0016] of the specification as published.

The present amended Claims now also refer to "one or more homeopathic dilutions of the potentiated form of antibodies to interferon being produced by a homeopathic potentiation technology". Homeopathic dilutions and homeopathic technology have been known in the field of homeopathy in the US to anyone of average skill in that field for almost 200 years, as written in the referenced NIH report. Paragraph [0016] of the specification as originally filed describes the homeopathic potentiation technology of producing homeopathic dilutions (decimal dilutions and centesimal dilutions, as well as simultaneous shaking). Additionally, enclosed with this response is a PDF file is a copy of the English language translation of the German Homeopathic Pharmacopoeia (1978, British Homeopathic Association, 5th Supplement of 1991), which

has extensive description of the potentization technique and various types of homeopathic dilutions. Applicants believe that the proposed amendments alternatively define the claimed invention in a precise and definite manner.

Claims 1-3 were rejected under 35 U.S.C. 102(e) over Chuntharapai *et al.* (US Patent No. 7,087,726). This rejection is respectfully traversed for the following reasons.

It is well established that a claim is anticipated under 35 U.S.C. §102, only if each and every element of the claim is found in a single prior art reference.[1] Moreover, to anticipate a claim under 35 U.S.C. §102, a single source must contain each and every element of the claim "arranged as in the claim."[2, 3] Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference.4 If each and every element of a claim is not found in a single reference, there can be no anticipation.

The Patent Office wrote that "the reference teach a medicament comprising the anti-IFN alpha antibody, wherein the medicament is administered in low or ultra low doses…". Applicants respectfully bring to the attention of the Patent Office the fact that the Chuntharapai patent teaches antibodies that bind to the interferon. For example, lines 1-5 of Col. 4 of Chuntharapai says (emphasis added):

> In one aspect, the invention provides an anti-human IFN-α monoclonal antibody which binds to and neutralizes a biological activity of at least human IFN- α subtypes IFN-1, IFN- α2, IFN- α4, IFN- α5, IFN- α8, IFN- α10, and IFN- α21.

Or, Col. 4 lines 19-27 of Chuntharapai says (emphasis added):

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1 *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

2 *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

3 *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q. 2d 1766, 1768 (Fed. Cir. 1987), cert. denied, 484 U.S. 1007 (1988).

4 *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 227 U.S.P.Q. 773, 777 (Fed. Cir. 1985).

> The biological activity of the subject human IFN- α's may be IFNAR2-binding activity. In a particular embodiment, the invention provides an anti-human IFN- α monoclonal antibody is capable of binding to and blocking at least 60%, or at least 70%, preferably at least 75%, more preferably at least 80%, even more preferably at least 85%, still more preferably at least 90%, still more preferably at least 95%, most preferably at least 99% of the IFNAR2-binding activity of all, or substantially all human IFN- α subtypes.

Contrary to the disclosure of the Chuntharapai patent, the present invention as claimed in amended independent Claim 1 specifies that potentiated form of antibodies to interferon prepared as homeopathic dilutions do not bind and suppress the activity of the interferon. As disclosed in paragraph [0010] of the specification supporting Claim 1 (emphasis added):

> [0010] The agent prepared according to the present invention is a new immunotropic pharmacologic preparation possessing pronounced specific pharmacologic activity, free of side effects, retention of therapeutic action, environmental purity, and low manufacturing costs. In contrast to non-activated forms of antibodies used, among other forms, in small doses, the homeopathically activated (potentised) antibodies to interferon feature an action that <u>does not suppress the activity of endogenous interferon</u>; the activated antibodies act more often synergistically (unidirectionally) with interferon and enhance, among other things, the induction of various forms of endogenous interferon.

The potentiated form of antibodies prepared in accordance with the homeopathic technology is a preparation different from just some non-activated and non-potentiated preparation containing antibodies. To repeat what has already been submitted above, homeopathic remedies are often so highly diluted that not one molecule of the original natural substance remains in the dilution. Potentiated diluted remedy is believed (without being committed to any specific scientific theory) to have modified properties of the solvent molecules or the clusters of the solvent molecules to cause therapeutic effect. While no definite scientific theory exists to explain how potentiated remedies work, it has been known that they work, along with the well known term "potentiated", defining such remedies. As claimed in independent Claim 1, the propertied of the claimed potentiated

form of antibodies to interferon are different at least in that the potentiated form does not suppress the activity of the interferon.

Applicants assert that no disclosure of the potentiated form comprised of one or more homeopathic dilutions is disclosed in Chuntharapai. That patent had no disclosure of the homeopathic dilutions (homeopathic doses) of the potentiated antibodies prepared by homeopathic technology. The degrees of dilution in Chuntharapai are not homeopathic dilutions (not decimal or centesimal dilutions), so no teaching or suggestion or motivation to use homeopathic dilutions of potentiated form of antibodies could be found in that patent.

Therefore, Claim1 and its dependent Claims 2 and 6 in the present application comply with the requirements of 35 U.S.C. 102(e) and are patentable over the cited patent.

Claims 1-3 were rejected under 35 U.S.C. 103(a) over Chuntharapai *et al.* (US Patent No. 7,087,726) in view of Cavazza (US Patent No. 5,683,712). This rejection is respectfully traversed for the following reasons.

For an obviousness rejection to be proper, the Patent Office must meet the burden of establishing a prima facie case of obviousness. The Patent Office must meet the burden of establishing that all elements of the invention are disclosed in the cited publications, which must have a suggestion, teaching or motivation for one of ordinary skill in the art to modify a reference or combined references.[5] The cited publications should explicitly provide a reasonable expectation of success, determined from the position of one of ordinary skill in the art at the time the invention was made.[6]

The Patent Office wrote with regard to the Cavazza patent that "Cavazza teaches how to prepare the active ingredients by a process called potentization consisting in a

5 In re Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).
6 In re Fine, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970); Amgen v. Chugai Pharmaceuticals Co., 18 U.S.P.Q.2d, 1016, 1023 (Fed. Cir. 1996).

succession of dilution which results in an extremely low or ultra low dose of the active ingredient…"

Applicants respectfully assert that it is not even Cavazza who teaches what potentization is. As it has already been presented above, the concept of homeopathic dilution and potentization has been known in the past even before Cavazza. Applicants do not claim to invent potentization as such, as mentioned in Cavazza. Cavazza teaches a patch for transdermal administration of medications, including homeopathic medications, but Cavazza says absolutely nothing else about what these homeopathic medications are or could be and how the antibodies in the homeopathic dilutions relate to the antigen and what their effect on the antigen is. The fact that Cavazza mentions homeopathic dilutions does not cure the lack of disclosure of each and every element of Claim 1 in Chuntharapai, as argued above As presented in the Rule 132 Declaration of Oleg Epshtein (paragraph 8) enclosed with this response, the discovery of the inventors as claimed in amended independent Claim 1 is that the homeopathic dilutions of the potentiated form of antibodies to interferon do not suppress the activity of the antigen (interferon), as is traditionally known. The combination of Cavazza and Chuntharapai discloses no such claim elements or such effect.

Therefore, Applicants respectfully assert that amended independent Claim 1 and its dependent Claim 2 and 6 comply with the requirements of 35 U.S.C. 103(a) and are patentable over the cited publications.

Furthermore, none of the cited publications discloses a medicament with immunotropic activity effective in treating a disease of viral etiology and comprised of homeopathic dilutions as claimed in amended independent Claim 1. To further support this aspect of the invention, Applicants enclose additional evidence of efficacy of the claimed medicament in the form of an enclosed Declaration of inventor Oleg Epshtein under 37 CFR 132. Applicants also assert that the non-obviousness of the claimed invention is additionally supported by the data of solid commercial success, as reflected in the enclosed Declaration of inventor Oleg Epshtein under 37 CFR 132. Therefore,

Applicants respectfully assert that amended independent Claim 1 and its dependent Claims comply with the requirements of 35 U.S.C. 103(a) and are patentable over the cited publications.

It is believed that the present application is in condition for allowance. A Notice of Allowance is respectfully solicited. Should any questions arise, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

HOUSTON ELISEEVA LLP

By /Maria Eliseeva/
Maria M. Eliseeva
Registration No.: 43,328
Tel.: 781 863 9991; Fax: 781 863 9931

4 Militia Drive, Suite 4
Lexington, Massachusetts 02421
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